CASE 4-20921B/C1

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE APPLICATION OF
WAGNER ET AL.
APPLICATION NO: Not Yet Assigned
FILED: Herewith
FOR: SOLID ORAL DOSAGE FORMS OF VALSARTAN

Art Unit: 1615
Examiner: Di Nola Baron, L.

Assistant Commissioner for Patents
Washington, D.C. 20231

PRELIMINARY AMENDMENT

Sir:

Kindly enter the following preliminary amendment prior to calculating the filing fee for the application.

IN THE SPECIFICATION

On page 1, after the title and before the first paragraph of the specification, please insert:

-- This application is a continuation of U.S. Application 09/202,805, filed May 7, 1999, which is a 371 of International Application PCT/EP97/03172, filed June 18, 1997. --

Please replace the first line of text (title) on page 1, with the following:
-- SOLID ORAL DOSAGE FORMS OF VALSARTAN --

Please replace the third paragraph on page 6, with the following rewritten paragraph:

-- Thus, where accelerated release is desired, e.g. about 90% release within a ten minute, more particularly a five minute period, a disintegrant such as crosslinked polyvinyl pyrrolidone, for example those products known under the registered trade marks Polyplasdone®XL or Kollidon®CL, in particular having a molecular weight in excess of 1 000 000, more particularly having a particle size distribution of less than 400 microns or less than 74 microns, or reactive additives (effervescent mixtures) that effect rapid disintegration of the tablet in the presence of water, for example so-called

effervescent tablets that contain an acid in solid form, typically citric acid, which acts in water on a base containing chemically combined carbon dioxide, for example sodium hydrogencarbonate or sodium carbonate, and releases carbon dioxide could be used. --

IN THE CLAIMS

Please cancel claims 1-27.

Please add the following new claims:

28. A compressed solid dosage form comprising
    (a) an active agent comprising an effective amount of valsartan or a pharmaceutically acceptable salt thereof; and,
    (b) at least one pharmaceutically acceptable additive

    wherein the active agent is present in an amount of more than 35% by weight based on the total weight of the compressed solid dosage form and wherein said dosage form exhibits accelerated release of the active agent.

29. The compressed solid dosage form according to claim 28 wherein the accelerated release constitutes about 90% release within a 10 minute, more particularly, a 5 minute period.

30. The compressed solid dosage form according to claim 28 wherein the additive is microcrystalline cellulose, cross-linked polyvinyl pyrrolidone, pregelatinized starch or hydroxypropyl cellulose.

31. The compressed solid dosage form according to claim 28 wherein the additive is an acid in a solid form.

32. The compressed solid dosage form according to claim 28 wherein the additive is citric acid.

33. A compressed solid dosage form comprising an active agent comprising an effective amount of valsartan or a pharmaceutically acceptable salt thereof; an effective amount of HCTZ; and, at least one pharmaceutically acceptable additive wherein the active agent is present in an amount of more than 35% by weight based on the total weight of the compressed solid

dosage form and wherein said dosage form exhibits accelerated release of the active agent.

34. The compressed solid dosage form according to claim 33 wherein the accelerated release constitutes about 90% release within a 10 minute, more particularly, a 5 minute period.

35. The compressed solid dosage form according to claim 33 wherein the additive is microcrystalline cellulose, cross-linked polyvinyl pyrrolidone, pregelatinized starch or hydroxypropyl cellulose.

36. The compressed solid dosage form according to claim 33 wherein the additive is an acid in solid form.

37. The compressed solid dosage form according to claim 33 wherein the additive is citric acid.

38. A compressed solid dosage form comprising

(a) an active agent comprising an effective amount of valsartan or a pharmaceutically acceptable salt thereof; and,

(b) at least one pharmaceutically acceptable additive

wherein the active agent is present in an amount of more than 35% by weight based on the total weight of the compressed solid dosage form, and wherein said dosage form exhibits delayed release of the active agent.

39. The solid dosage form according to claim 38 wherein the additive is hydroxypropyl methylcellulose.

40. A compressed solid dosage form comprising an active agent comprising an effective amount of valsartan or a pharmaceutically acceptable salt thereof; an effective amount of HCTZ; and, at least one pharmaceutically acceptable additive wherein the active agent is present in an amount of more than 35% by weight based on the total weight of the compressed solid dosage form and wherein said dosage form exhibits delayed release of the active agent.

41. The solid dosage form according to claim 40 wherein the additive is hydroxypropyl methylcellulose.

REMARKS

Attached hereto is a marked-up version of the changes made to the specification and claims by the current amendment. The attached page is captioned **"Version with markings to show changes made."**

Examination of this application and early allowance are respectfully requested.

Respectfully submitted,

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Date: August 1, 2001

VERSION WITH MARKINGS TO SHOW CHANGES MADE

In the specification:

The first line of text (title) on page 1 has been amended as follows:

-- SOLID ORAL DOSAGE FORMS OF VALSARTAN --

The third paragraph on page 6 has been amended as follows:

Thus, where accelerated release is desired, e.g. about 90% release within a ten minute, more particularly a five minute period, a disintegrant such as crosslinked polyvinyl pyrrolidone, for example those products known under the registered trade marks Polyplasdone®XL or Kollidon®CL, in particular having a molecular weight in excess of 1 000 000, more particularly having a particle size distribution of less than 400 microns or less than 74 microns, or reactive additives (effervescent mixtures) that effect rapid disintegration of the tablet in the presence of water, for example so-called effervescent tablets that contain an acid in solid form, typically citric acid, which acts in water on a base containing chemically combined carbon dioxide, for example sodium hydrogencarbonate or sodium carbonate, and releases carbon dioxide could be used.

In the claims:

Claims 1-27 have been canceled.

New claims 28-41 have been added.